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August 12, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No: 2004N-0264

Dear Sir or Madame:

Keystone Foods LLC, a processor of meat and poultry products, wishes to take this opportunity to submit comments on the Advance Notice of Proposed Rulemaking (ANPRM). 69 Fed. Reg. 42288 (July 14, 2004). After the identification of bovine spongiform encephalopathy (BSE) in the second indigenous North American cow, the U.S. Department of Agriculture (USDA) responded rapidly to implement measures to protect public health. We are of the opinion that it is time for the Food and Drug Administration to take actions necessary to further strengthen firewalls against recycling of the BSE agent within North America. Assuring that amplification of the BSE agent will not take place will boost consumer confidence in the safety of US beef and pharmaceutical products.

While the ANPRM asks for answers or opinions on several issues, we will only comment at this time on the following items:

- Removal of SRMs from animal feed
- Definition of SRMs
- Support for risk assessment

Removal of SRMs from all animal feed

We feel that for the FDA to provide a more comprehensive and protective feed ban, specified risk materials (SRMs) and deadstock must be removed from all animal feed and that legal exemptions which allow ruminant protein to be fed back to ruminants (with the exception of milk) should be discontinued.[1] Such a measure should also effectively block potentially infectious material from being reintroduced to animals through poultry litter, plate waste, cross feeding of non ruminant rations to ruminants, and feed contamination (non ruminant to ruminant).

[1] The exemption for milk and milk products from the existing feed ban should be retained, because there is no scientific evidence that BSE can be transmitted through milk.

A number of authoritative bodies also agree with the position that removing SRMs and deadstock from all animal feed would reduce the BSE risk within the US.

Harvard/Tuskegee BSE Risk Assessment

Per the Executive Summary of its 2001 release, the Harvard/Tuskegee Study states, "Specific pathways or practices that would contribute the most to the spread of BSE if it were introduced into the U.S. relate to compliance with the FDA feed ban and include misfeeding on the farm and the mislabeling of feed and feed products prohibited for consumption by cattle. The disposition of cattle that die on the farm would also have a substantial influence on the spread of BSE if this disease were introduced into the U.S."

The report continues:

- "Our evaluation of potential risk mitigation actions highlights potential measures to further reduce the already low likelihood that BSE could spread to cattle or contaminate human food if it were to arise. Prohibiting the rendering of animals that die on the farm, possibly of BSE, removes a great deal of potential contamination in the animal feed chain and reduces average predicted cases of BSE following introduction of ten infected cattle by 77%. Implementation of a UK-style ban on specified risk material (*e.g.*, spinal cords, brains, vertebral columns) from both human food and animal feed reduces the predicted number of BSE cases in cattle by 80% and the potential human exposure by 95%."

- "The disposition of cattle that die on the farm would also have a substantial influence on the spread of BSE if the disease were introduced." The base case scenario showed that the mean total number of ID50s (*i.e.*, dosage sufficient to infect 50 percent of exposed cattle) from healthy animals at slaughter presented to the food/feed system was 1500. The mean total number of ID50s from adult cattle deadstock presented to the feed system was 37,000. This illustrates the risk of "4D cattle" (*i.e.*, deadstock).

Harvard Risk Assessment, 2001, Appendix 3A Base Case.

Subcommittee to the USDA's Foreign Animal and Poultry Disease Advisory Committee

An international panel of transmissible spongiform encephalopathy (TSE) experts appointed by Secretary of Agriculture Ann M. Veneman as a subcommittee to the Foreign Animal and Poultry Disease Advisory Committee issued a report in February 2004 which stated:

> "... given the epidemiological evidence indicating that BSE agent was already circulating in ruminant feed prior to the feed ban in 1997, and the integration of the North American cattle and feed industries, strong consideration should be given to excluding all SRM from **both the human**

food and animal feed supplies.

"Considering the BSE situation in North America, the subcommittee believes the partial (ruminant to ruminant) feed ban that is currently in place is insufficient to prevent exposure of cattle to the BSE agent."

Secretary's Advisory Committee on Foreign Animal and Poultry Diseases' Subcommittee on the United States' Response to the Detection of a Case of Bovine Spongiform Encephalopathy, Report on Measures Relating to Bovine Spongiform Encephalopathy (BSE) in the United States, 2 February 2004, p. 8 (emphasis added).

In conclusion, we urge the FDA to issue without undue delay additional regulations prohibiting the inclusion of SRMs and deadstock in feed for all animals. We further urge FDA to discontinue all of the exemptions to the existing feed ban (with the exception of the exemption for milk), which still allow the feeding of ruminant protein to ruminants.

Definition of SRMs

Specified Risk Materials, as defined by the USDA, are tissues from bovine animals over 30 months of age that, in a BSE infected animal, are known to either harbor BSE infectivity or to be closely associated with infectivity. In addition, the small intestine and tonsils of bovines of all ages are included in the definition of SRMs. If appropriate feeding practices are not followed, SRMs may introduce BSE infectivity and continue to provide a source of animal feed contamination.

We recognize that the science of detection of cattle that have been infected with BSE continues to evolve. While there is no current test available to reliably detect an infected animal in the live state, theoretically this is possible. In the event that a test is developed that will reliably and with adequate sensitivity, detect a BSE infected animal prior to slaughter, then tissues from animals that are tested negative for BSE by such a test, should not be classified as SRMs. While we recognize that this is only a theoretical consideration at present, we encourage FDA not to close the door on such a future consideration. We believe that it would be far more protective of public health to test all animals over 30 months of age (when such a test becomes available) than to depend on current and proposed measures to preclude BSE.

In addition, we are aware of several research efforts targeted at the deactivation of the BSE agent. Should any of these projects prove successful in rendering SRMs as not infectious for BSE, we respectfully submit that these materials would no longer be designated as Specified Risk Materials, regardless of age of animals from which they are derived.

Support for Risk Assessment

Risk based decision making has become a hallmark of contemporary policy making within US regulatory agencies. We encourage the agency to conduct a risk assessment to assist in the policy discussions relative to the consideration of risk management strategies or policies. We refer here specifically to information now available on the infectivity of

various tissues. Not all tissues currently identified as SRM are equally infective in terms of transmission of BSE. It may be possible to determine alternative uses for certain SRM based on outputs of a risk assessment that considers relative reductions of infectivity due to various treatments. This risk assessment should also consider all existing and potential treatments to reduce infectivity as well as alternative uses for potentially infectious tissues. The risk estimate from each scenario should also be considered relative to the cost of each in the evaluation of risk management options.

Thank you for the opportunity to comment.

Dane Bernard

Respectfully submitted,

Dane Bernard
Vice President, Food Safety
Keystone Foods LLC